Evaluation of the Functional Outcome of Frozen Shoulder Managed by Hydraulic Capsular Distension -A Prospective Study

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Abstract

Background: Frozen shoulder is a clinical condition characterized by restriction of active and passive movements usually due to an intrinsic disorder of the shoulder. This affects the day-to-day activities of a person.

Objectives: In this study, we try to find out the effect of hydrodilation of the affected shoulder joint and further the improvement in the function of the same.

Patients and methods: This study was performed on 30 patients diagnosed with a unilateral frozen shoulder. All the patients were treated with hydraulic capsular distension followed by manipulation of the shoulder under general anesthesia. The results of the treatment were documented at intervals of 1 and 6 months.

Results: All the patients were followed up at 1 and 6 months using the Shoulder Pain and Disability (SPADI) Score. We have lost 2 patients (6.67%) in follow-up. On follow-up, the SPADI Score was found to be reduced by 45%. There was an increase in the range of movements in 50% of patients. Out of 28 who were followed, 18 (64.28%) had excellent, 9 (32.14%) were rated good, 1 (3.51%) had fair, and zero had poor outcomes at 1 month. The outcome at the 6-month follow-up. 14 (50%) had excellent, 8 (28.57) had good, 5 (17.85) had fair, and 1 (3.57) had a poor outcome.

Conclusion: In our study, we conclude that hydrodilatation in the management of frozen shoulder is a reliable, safe, and cost-effective method. The procedure is usually associated with very minimal complications and a good prognosis.

Keywords: Frozen shoulder; Adhesive capsulitis; Steroid.

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Introduction

Frozen shoulder is a clinical condition characterized by the restriction of active and passive movements due to an intrinsic disorder of the shoulder. Frozen shoulder is also called scapulo-humeral periarthritis and adhesive capsulitis. A frozen shoulder initially begins with a painful phase called the freezing phase; this stage lasts for about three months. Then the disease progresses to a painless phase called the frozen phase where the pain decreases but the movements both active and passive are severely restricted, this phase might last up to nine months. Further, the disease progresses to a remodeling phase called the thawing phase where patients begin to report an improvement in the range of motion, this phase can last up to 18 months. The stage at which the patient currently is may influence the treatment required, with steroid therapy preferred in the freezing phase, while arthrolysis may be needed in the frozen phase (**Rymaruk et al ., 2017).**

According to **Neviaser (1983)** adhesive capsulitis is a contracted thickened joint capsule tightly around the humeral head with the absence of synovial fluid and chronic inflammatory changes within the sub-synovial layer of the capsule.

It is an idiopathic condition, but cytokinin, growth factor beta 1 and metalloproteinase have shown some role in its cascade. **Inayat et al (2017)** suggested that periarthritis is 5 times more prevalent in diabetic patients and the glycosylated hemoglobin (HBA_1C) level can be correlated. Other risk factors included female gender, age >50 years, cervical disc disease, hyperthyroidism, prolonged immobilization, stroke, Myocardial infarction, autoimmune disorders and trauma. Nearly 65% to 75% of affected patients were found to be female. Around 20% to 30% of patients were found to have the same condition on the opposite side.

Andren et al (1965) developed a classification system for frozen shoulder based on the presence or absence of an inciting event. Primary frozen shoulders are characterized by a lack of a triggering event and no abnormal findings except for limited motion. Secondary frozen shoulders, on the other hand, occur after traumatic injuries.

Females in their fourth to sixth decades most commonly are affected by frozen shoulder. It can be classified as per its etiology into primary idiopathic or secondary that can be further classified as intrinsic, which may be due to pathologies related to the shoulder joint and a extrinsic type, which is unrelated to shoulder joint pathologies and may be due to systemic causes such as diabetes and thyroid dysfunction. The incidence of frozen shoulder in a diabetic may be up to 20 percent as compared to 5 percent in the general population (**Sharma et al.,2011).**

Shoulder stiffness after surgical intervention leads to secondary frozen shoulder but their clinical course and treatment are not the same and are not discussed here. There is no specific criterion for the diagnosis of a frozen shoulder. We observed that initially internal rotation was frequently affected followed by restriction of flexion and external rotation. Most patients can internally rotate up to the sternum, and patients have 50% restriction in external rotation and less than 90% of abduction.

In this study, we aim to evaluate the functional outcome of frozen shoulder managed by hydraulic capsular distention.

Patients and methods

Ethical and scientific committee clearance was received before the start of the study, and proper written and explained consent was obtained.

The study was performed from January 2022 to December 2022 on 30 patients who were diagnosed clinically and

radiographically with a frozen shoulder. Follow up ranged from 6 to 8 months with mean being 7 months, and data was recorded at 1- and 6-months post-procedure.

Patients with unilateral shoulder stiffness for more than 3 months, ages between 40 to 60 years, restriction of range of movement of the shoulder around 30 degrees in two or more planes, patients who had taken extensive physiotherapy and analgesics before this treatment and were not happy with the results were included in the study. Patients less than 40 years and more than 60 years, with fractures around the shoulder or with prolonged immobilization were excluded from the study.

Pre-procedural assessment was done using the SPADI Score with a degree of range of movements documented, and X-ray and MRI was performed and documented.

Materials required are a 23G spinal needle, inj lignocaine (2%), inj methylprednisolone (40mg), distilled water, syringes (2, 5 and 20 cc) and a 3-way adaptor.

Procedure

Under general anesthesia, under all aseptic precautions, patients in the lateral decubitus position, bony landmarks marked with a sterile skin marker pen (**Fig.1**). A 23G spinal needle was inserted 2-3cm inferior to the angle (posterolateral corner) of the acromion and was aimed at the coracoid process anteromedially. The needle should pass freely into the joint space without encountering any resistance. After appropriate positioning of the needle a 3-way adapter is attached to the needle and 10cc of 2% Lignocaine is injected into the joint(**Fig.2**).

After 5 minutes 30-40 ml of normal saline was gradually injected into the joint and as the intra-articular pressure rises, a sudden pop could be appreciated(**Fig.3**).

Followed by a 1ml of Methylprednisolone (Depo-Medrol) 40mg/ml is injected into the joint (**Fig.4**). Post-infiltration of the joint is immediately put through the full range of motion. Shoulder ROM exercises, and pendulum exercises, wheel exercises were commenced immediately post-procedure.

Fig.1. shows surface markings

Fig.2. shows local anesthetic injection

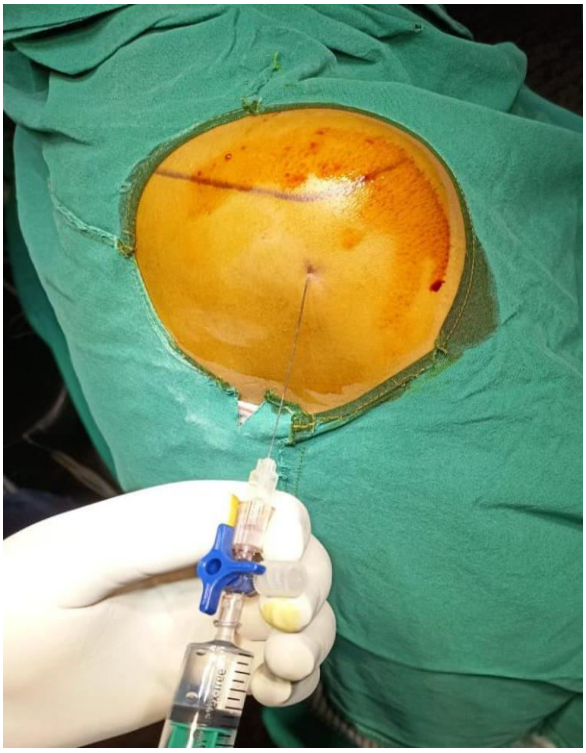

Fig.3. showing hydrodistension

Fig.4. showing local steroid infiltration

Observation

In our study, we used the SPADI score, which has 5 questions related to pain and 8 questions related to disability, which includes but is not limited to various problems encountered by the patient with the usage of their affected shoulder over the past week. Questions in the pain scale are graded from no pain at all to the worst pain imaginable, similarly, in the disability section it is graded from no difficulty to so difficult that it requires help. Item scores for each section are averaged to produce separate subscale scores ranging from 0 to 100. A SPADI total score ranging from 0 (best) to 100 (worst) is then produced by averaging the two subscale scores.

Many patients in our study had difficulty in doing their routine day-to-day activities like washing hair, buttoning shirt buttons, and placing objects high on a shelf. Patients had a remarkable improvement in daily routine activities post hydrodilatation which was assessed by the SPADI Score and the results were statistically significant.

Statistical analysis

The compilation of data was done in Microsoft Excel and analyzed by using a simple table. Significant differences among groups were determined using Student's t-test. All differences were determined to be significant at the $p<0.05$ level

Results

Out of 30 cases in our study, 17 (56.67%) cases were female and 13 cases (43.33%) were male. All the patients had a follow-up at 1 and 6 months using the SPADI Score. We have lost 2 patients (6.67%) in the follow-up. The right side of 18 patients (60%) and the left side of 12 patients (40%) were found to be involved. In 23 patients (76.67%) it was associated with type 2 diabetic mellitus, 18 patients had hypertension, and 16 patients had hypothyroidism. The mean age of the affected individual in our study was 52

years. There was reoccurrence in 4 patients (13.3%) who also had type 2 diabetic mellitus. On follow-up, the patients were evaluated using the SPADI Score and were found to be significantly reduced by 45%. There is a significant increase in the range of movements in 50% of patients. Out of 28 patients who were followed, 18 patients (64.28%) had excellent, 9 patients (32.14%) had good, 1 patient (3.51%) had fair, and zero patients had poor outcomes at 1 month, as shown in (**Table.1)**. The outcome at the 6-month follow-up of 14 patients (50%) had excellent, 8 patients (28.57) had good, 5 patients (17.85) had fair, and 1 patient (3.57) had a poor outcome, as depicted in (**Table.1)**.

Table 1. SPADI Score results at pre injection and at 1 and 6 months follow up

Outcome category SPADI Score	Pre procedure	1-month post procedure	6-month post procedure	p-value	
				Pre- 1 month post	Pre- 6-month post
Excellent	0	18	14	0.002	0.026
Good	0	9	8		
Fair	3	1	5		
Poor	27	0	0		

Comparison between pre- and post-procedure data at 1 month, performing a paired t-test, the p-value for this comparison is approximately 0.002. Comparison between pre and post-procedure data at 6 months, performing a paired t-test, the p-value for this comparison is approximately 0.026.

But overall, the p-value is statistically significant at both 1 and 6 months as compared to the pre-procedure values, which shows hydrodilatation plays an important role in a better lifestyle of the patient.

Discussion

Frozen shoulder is a common disorder that, if not treated properly results in significant pain and disability. In the literature, treatment of frozen shoulder ranges from rest, physiotherapy, and steroid injection to open surgical release.

A study by **Tveita et al. (2006)** was done to compare the outcomes of two groups who experienced frozen shoulder, one was treated with hydrodilatation with 20mg tiramcinalone, 4 ml 0.5 percent bupivacaine and 10 ml saline. In the other group, patients were treated with a fortnightly image guided 20mg triamcinalone with 4 ml 0.5 percent bupivacaine for 6 weeks. Both groups had significant improvement from the baseline, as could be expected for patients with frozen shoulder.

A study by **Bell et al. (2003)** involved 109 patients with frozen shoulder which were managed by hydrodilatation in 106 patients over 3 years. There were 15 of the above patients who were diabetic. They used a mixture involving 4mg betamethasone, 2 ml 2% lignocaine and saline volume, which ranged between 10 to 55 ml as needed for capsular rupture. Patients were then followed up with at two and four months. VAS was used to assess pain score and clinical range of motion was documented at each follow-up. Patients at 2 months had an improvement of 25 degrees of abduction, 30 degrees of external rotation and 40 degrees of elevation, which were the mean scores, in non-diabetic patients. These mean scores were higher compared to the diabetic patients in general. On assessment of pain score, most patients had moderate pain which improved to nil at 2 months.

In the study by **Quraishi et al. (2007)** they treated 17 patients with manipulation under anesthesia and 19 patients were treated with hydrodilatation with an injection of steroids, local anesthetic and varying amounts of the saline mixture. Patients were followed-up and the study demonstrated patient satisfaction to be 94 percent in hydrodilatation compared to 81 percent in the manipulation group.

The study by **Jacob et al. (1991)** compared three frozen shoulder interventions in a prospective randomized study. Shoulder distension with air, intra-articular steroid injection and distension with air and steroid. They found that intra articular steroid injection and distension with air and steroid are superior to distension with air and no significant difference between intra-articular steroid injection and distension with air and steroid. In our study, we found that distension with saline and steroid were showing good results.

Buchbinder et al. (2004) conducted randomized double-blind trials comparing placebo to shoulder joint distension with normal saline plus steroid. This study showed significant short-term improvement in pain and disability with distension with normal saline plus steroid over the placebo.

In a study by **Gavant et al. (1994)** sixteen patients with adhesive capsulitis of the shoulder were treated with capsular distension with intraarticular injection of 30mL mixture containing 8mL of 1% lidocaine, 2mL of corticosteroid, and 20mL of radiocontrast material. A capsular tear occurred in all the cases during arthrography. The rupture occurred either at the subscapular bursa or the subacromial bursa. Thirteen patients had immediate pain relief and increased shoulder movements. This improvement was even noted at 6 months. Disruption of the constricted capsule by hydraulic distension seems to be the mechanism for achieving symptomatic relief in adhesive capsulitis.

The **Ghauri et al. (2009)** study included 2 groups of 30 patients each, the first group was treated with hydraulic distension with 50 ml normal saline and a steroid and the second group was only treated with intra-articular steroid injection. At the end of 45 days, the first group had excellent pain relief and good movements and returned to routine activities, but the second group patients had immediate pain relief but could not return to normal routine activities due to less improvement of movements. The study recommended that patients with frozen shoulder should be treated with hydraulic distention under local anesthesia with steroid because this technique is safe and cost-effective and provides immediate relief of symptoms. In our study, we also used the same technique of hydraulic distention under local anesthesia with a steroid.

The study by **Singh et al. (2013)** concluded all 30 patients in a group who were treated with hydrodilatation noted immediate pain relief with an excellent return of range of motion (ROM) and resumption of normal sleep. At 45 days of follow-up all patients had returned to their routine activities. Most of the patients got excellent ROM and pain relief. Similar to most of the patients in our study.

Clement et al. (2013) used a mixture of steroid (40 mg/80 mg triamcinolone depending on whether they were diabetic or not) and local anesthetic (10 ml 1% lidocaine) with 40 ml saline, in their study. At 1-month post-procedure, the follow-up showed that 55 percent of patients had normal or near normal shoulder function. The findings were similar to our study as well. **Rymaruk et al. (2017)** concluded that hydrodilatation can be encouraged for short-term care in individuals who are not improving or for whom watchful waiting is

impractical. Patients with diabetes need to be advised about the expected worse results compared to the non-diabetic group. Hydrodilatation can be used as a follow-up therapy in patients who have not fully recovered.

Ainen et al. (2020) concluded that the use of USG hydrodilatation procedure as a safe and effective intervention for adhesive capsulitis patients resistant to conservative treatment. Improvements in shoulder ROM and pain were evident in the short-term (6 weeks), supporting its utilization before surgical consideration.

Challoumas et al. (2020) in their study stated that improved outcomes are associated with the early use of intraarticular corticosteroids in patients with frozen shoulder who have had it for less than a year. To increase the likelihood of recovery, a home exercise programme should be used in conjunction with this treatment.

Choudhary et al. (2022) Compared to intra-articular corticosteroid, hydrodilatation with corticosteroid offers superior pain and range of motion alleviation for frozen shoulder. When compared to intra-articular corticosteroid, hydrodilatation is a preferable therapy option due to its good results predictability.

In our study of 30 patients, all the patients were followed-up with at 1 and 6 months using the SPADI Score. There is a high prevalence associated with comorbidity (T_2DM/HTN/Thyroid disorders). There was a reoccurrence in 4 patients who also had type 2 diabetic mellitus. On the follow-up, patients were evaluated using SPADI Score and were found to be significantly reduced by 45%. There is a significant increase in the range of movements in 50% of patients. In our study, we found a good functional outcome.

Limitations: As a single Centre study, it will need a more extensive multicentric analysis to get a clearer picture. Long-term follow-up is needed for assessment of the effect of the treatment. A study is also needed to further assess the effect of diabetes on the treatment and prognosis of frozen shoulder.

Conclusion

Frozen shoulder cases that are mild can be managed and the problem can be resolved with proper physiotherapy and analgesia. However, many patients especially in the moderate to severe stages may not respond to this treatment. In those cases, watchful waiting is not practical and hydrodilatation can be used as a modality of treatment. Diabetic patients may have an inferior outcome as compared to non-diabetic patient and may have chances of relapse as well.

In our study, we conclude that hydro dilatation in the management of frozen shoulder is a reliable, safe and cost-effective method. If performed under total aseptic conditions it is usually associated with very minimal complications and a good prognosis.

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